

# Exhibit 21

## Clinical plaque removing efficacy of a new power toothbrush

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**ABSTRACT:** *Purpose:* To evaluate the effect of adding a pulsating bristle action to the established oscillating/rotating action of the Braun Oral-B Ultra Plaque Remover (D9) on plaque removal. *Materials and Methods:* Plaque removal was evaluated using the modified Quigley-Hein Plaque Index in a double blind randomized, cross-over study involving 32 healthy volunteers without any dental training. After 2 weeks use of the D9 during which time subjects received training in its use, subjects abstained from oral hygiene for 48 hours. They were then assessed for plaque after which they brushed their teeth using an experimental toothbrush randomly set to either the D9 oscillating/rotating action or to the new 3D action with an additional pulsating movement of the brush head in the direction of the long axis of the bristles. After brushing, plaque was again evaluated. Following a further 2 weeks of normal home use of the D9, subjects returned and the procedure was repeated using the brush set in the second mode. *Results:* Both toothbrush actions were found to be effective at removing plaque from all sites and surfaces in the mouth. The 3D action was consistently more effective than that of the D9, the difference being statistically significant for the whole mouth, the upper jaw, the lingual surfaces and for all interproximal sites, in particular in the upper jaw. (*Am J Dent* 1998;11:S13-S16).

**CLINICAL SIGNIFICANCE:** The additional pulsating action of the Braun Oral-B 3D Plaque Remover leads to a significantly greater removal of plaque, in particular from interproximal surfaces.

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### Introduction

The advantages of modern power toothbrushes are now well established, and many studies have shown their superiority over conventional manual toothbrushing.<sup>1,2</sup> Power toothbrushes enable most subjects to brush with a good technique irrespective of their individual skill and dexterity. They allow subjects to focus on where in the mouth they brush rather than how they brush, and perhaps most importantly they have been shown to enhance motivation.<sup>3</sup>

The evolution of the modern power toothbrush has taken place along a number of different paths, and today a wide range of effective brushes are available with different actions and brush head designs. However, because of this variability in design, all power toothbrushes cannot be considered equal, and while there is clear evidence of greater efficiency compared to manual toothbrushes,<sup>4,5</sup> there is less information available comparing different brands of power toothbrushes.<sup>1</sup>

Manufacturers of power toothbrushes continually seek new ways to improve the design and increase the efficiency of their brushes. Demonstrating these improvements in clinical efficacy is, however, not easy, as the margin of improvement may be relatively small.

One power toothbrush that has been extensively investigated and consistently shown to be more effective than a manual toothbrush and certain other brands of power toothbrushes is the Braun Oral-B Plaque Remover,<sup>6</sup> which features a small brush head with an oscillating/rotating action. The first Plaque Remover models (D5 & D7) operated at a frequency of 50 Hz and an angle of oscillation of 70°. By increasing the frequency to 63 Hz, and decreasing the angle

of oscillation to 60° (Braun Oral-B Ultra Plaque Remover - D9), cleaning efficiency was significantly increased. This improvement was demonstrated in a study using a novel laboratory robot,<sup>7</sup> which was developed in order to allow rapid evaluation of toothbrush developments,<sup>8</sup> and in a clinical study of stain removal.<sup>9</sup> The latest development of the Plaque Remover retains the oscillating/rotating action of the D9, but features an additional pulsating action in the direction of the long axis of the bristles (Braun Oral-B 3D Plaque Remover). This pulsating action was introduced in order to enhance cleaning of difficult to reach areas of the dentition such as occlusal fissures and interproximal sites. An initial robot study<sup>10</sup> has confirmed the success of this development, with significant advantages in favor of the 3D over the D9 being observed for all sites, including interproximal areas.

This study assessed the safety and efficacy of the 3D in a clinical setting and evaluated its efficiency compared to the D9. The study was unique in that a D9 was modified to allow the 3D action to be activated such that neither the subject nor the examiner was aware of which action was being tested. Thus the study was double blind, reducing the possibility of user bias.

### Materials and Methods

This was a double-blind, randomized, cross-over study involving healthy volunteers without any dental training. A total of 32 subjects (equal numbers of males and females) were included in the study. Their ages ranged from 18 to 49 years with a mean age of  $28.9 \pm 8$  years. Inclusion criteria included good general health, at least 20 natural teeth without a removable denture and no ongoing medication that might influence the gingival condition. Subjects were ex-

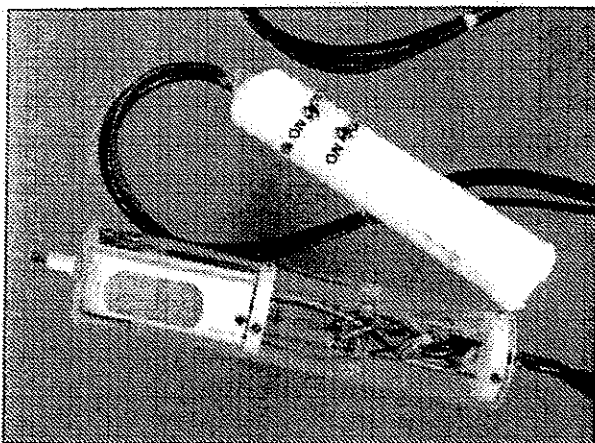


Fig. 1. The experimental power toothbrush with switchable D9/3D action.

cluded if any dental treatment was scheduled during the course of the study. All subjects gave their informed consent prior to commencement of the study.

At the start of the study all volunteers were given a Braun Oral-B Ultra Plaque Remover (D9) and with the aid of an instructional video were trained in its use. They were asked to use the D9 at home, and after 1 week they returned so that the investigator could check that they were using the device correctly. For the duration of the study, subjects were instructed to use only the power toothbrush for home oral hygiene. After a further week, subjects returned for the first phase of this cross-over study.

At the first appointment, volunteers were examined for evidence of soft tissue abrasion, and scored for visible plaque using a modification of the Quigley and Hein Index<sup>11</sup> where plaque was scored for six surfaces of the tooth, namely the mesiobuccal, buccal, distobuccal, mesiolingual, lingual and distolingual tooth surfaces. Plaque was disclosed prior to scoring with a 5% erythrosin solution (Plaviso<sup>®</sup>). The teeth and adjacent gingiva were lightly dried with compressed air after which the disclosing solution was applied without pressure using a foam pellet. Subjects then rinsed with water twice for 15 seconds. A professional prophylaxis was carried out, so that all subjects entered the study with a zero plaque score. They were then asked to refrain from any kind of oral hygiene for 48 hours. After this period, they returned and had their plaque again scored using the modified Quigley and Hein Index. Subjects then brushed for 2 minutes under supervision of a second examiner using a specially designed experimental power toothbrush based on the D9. This device (Fig. 1) had a switchable additional high frequency pulsating action in the direction of the long axis of the bristles. When set in this mode, the device had the action of the new Braun Oral-B 3D Plaque Remover. When not switched on, the device operated as a D9, with just an oscillating/rotating action. Subjects were randomly distributed into two groups, one starting the study with the toothbrush in the conventional mode (D9) and the other in the new mode with the additional pulsating action (3D). Throughout the study, both the subjects and the examiner

were unaware of what mode the brush was operating in and therefore the study was double-blind.

New brush heads were used for each volunteer with Blend-a-Med<sup>®</sup> toothpaste. After brushing, plaque was re-disclosed and the plaque index scored. Subjects were then dismissed for 14 days and instructed to only use their D9 power toothbrush for oral hygiene. Following a second prophylaxis and 48-hour period of abstinence from oral hygiene, the procedure was repeated, each subject using the toothbrush set in the other mode. Thus at the end of the study, each subject had brushed their teeth with the toothbrush in both settings. In addition to recording the plaque index, all subjects were photographed before and after brushing in order to provide a visual record of plaque.

Plaque reduction was analyzed for the following areas of the oral cavity: the whole mouth, the upper jaw, the lower jaw, all vestibular surfaces, all lingual surfaces, vestibular surfaces (upper jaw), lingual surfaces (upper jaw), vestibular surfaces (lower jaw), lingual surfaces (lower jaw), all interproximal surfaces, interproximal surfaces (upper jaw), and interproximal surfaces (lower jaw). The difference in plaque reduction with and without the additional pulsating action of the 3D was statistically analyzed using the Wilcoxon test at a significance level of 5%.

## Results

After brushing with the experimental power toothbrush in either D9 mode (oscillating/rotating) or 3D mode (oscillating/rotating + pulsating) for a period of 2 minutes, soft tissues were examined for evidence of trauma. Neither action was found to cause gingival abrasion and none of the subjects reported any discomfort during the study.

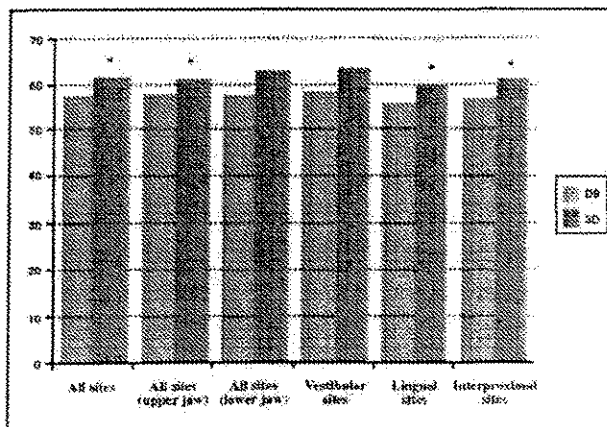
Both brush actions were effective at removing plaque from all sites in the mouth. The percentage reduction in plaque for the D9 ranged from a minimum of 55.4% (all lingual surfaces), to a maximum of 58.8% (vestibular surfaces on the upper jaw). For the 3D, the minimum value was 58.9% (interproximal surfaces on the upper jaw) and the maximum 65.2% (vestibular surfaces on the lower jaw). A comparison of results from the first and second phase of the study revealed that there was an apparent training effect, with more plaque removed from interproximal surfaces in the second phase of the study than in the first. This enhanced plaque removal was irrespective of which mode the power toothbrush was first used in.

The Table and Fig. 2 show the mean plaque scores before and after brushing for 2 minutes with the power toothbrush either in D9 or 3D mode. For all sites and surfaces evaluated, the 3D action was consistently more effective than the D9. For all sites combined (whole mouth) the D9 action reduced plaque by 57.3% from a pre-brushing score of 3.37 to 1.44. In 3D mode, plaque was reduced by 61.3% from 3.41 to 1.32. The difference between the two actions was statistically significant in favor of the 3D ( $P=0.004$ ). A similar advantage in favor of the 3D was observed for interproximal surfaces where the D9 action reduced plaque by 56.5% from 3.75 to 1.63, compared with a reduction of 60.5% with the 3D, from 3.77 to 1.49. As



Table. Plaque scores ( $\pm$ SEM) before and after brushing for 2 minutes using either the D9 action or the 3D action.

		Pre-brushing	Post-brushing	Reduction (%)	Group comparison
Whole mouth	D9	3.37 (0.38)	1.44 (0.53)	57.3	P = 0.004
	3D	3.41 (0.37)	1.32 (0.46)	61.3	
Upper jaw	D9	3.48 (0.41)	1.44 (0.57)	57.6	P = 0.002
	3D	3.44 (0.38)	1.35 (0.55)	60.8	
Lower jaw	D9	3.35 (0.44)	1.43 (0.62)	57.3	ns
	3D	3.38 (0.43)	1.27 (0.53)	62.4	
All vestibular surfaces	D9	3.80 (0.42)	1.57 (0.63)	58.7	ns
	3D	3.79 (0.44)	1.41 (0.63)	62.8	
All lingual surfaces	D9	2.94 (0.48)	1.31 (0.56)	55.4	P = 0.0005
	3D	3.03 (0.36)	1.22 (0.42)	59.7	
Vestibular surfaces (upper jaw)	D9	4.13 (0.47)	1.70 (0.70)	58.8	ns
	3D	4.14 (0.43)	1.62 (0.79)	60.9	
Lingual surfaces (upper jaw)	D9	2.60 (0.70)	1.18 (0.66)	55.6	P = 0.0015
	3D	2.73 (0.55)	1.09 (0.61)	60.1	
Vestibular surfaces (lower jaw)	D9	3.48 (0.58)	1.44 (0.70)	58.6	ns
	3D	3.45 (0.53)	1.20 (0.66)	65.2	
Lingual surfaces (lower jaw)	D9	3.23 (0.45)	1.42 (0.69)	55.9	P = 0.037
	3D	3.31 (0.41)	1.34 (0.55)	59.5	
All interproximal surfaces	D9	3.75 (0.42)	1.63 (0.63)	56.5	P = 0.009
	3D	3.77 (0.36)	1.49 (0.55)	60.5	
Interproximal surfaces (upper jaw)	D9	3.77 (0.47)	1.67 (0.69)	55.7	P = 0.003
	3D	3.80 (0.41)	1.56 (0.68)	58.9	
Interproximal surfaces (lower jaw)	D9	3.72 (0.47)	1.59 (0.72)	57.3	ns
	3D	3.72 (0.43)	1.40 (0.61)	62.4	

Fig. 2. Percentage plaque reduction after 2 minutes brushing. \*Statistically significant difference in favor of the 3D,  $P < 0.005$ .

for the whole mouth, this difference was statistically significant ( $P = 0.009$ ). Comparing the two actions, it can be seen that the 3D was numerically more effective at all sites and surfaces and that this difference was statistically significant ( $P < 0.05$ ) for the whole mouth, the upper jaw, all lingual surfaces, lingual surfaces in the upper jaw, lingual surfaces in the lower jaw, all interproximal surfaces and interproximal surfaces on the upper jaw.

## Discussion

It is clear that today's modern power toothbrushes are in most cases significantly better than manual brushes when used by ordinary subjects,<sup>1,12</sup> and their continuing development should offer the general public increasing potential to remove dental plaque and maintain good oral hygiene. It would be wrong, however, to assume that just because a power toothbrush is new that it is necessarily effective and safe, and it is therefore important that manufacturers fully evaluate all new developments.

One of the most recent developments in power toothbrushes has been the introduction of a new Plaque Remover by Braun, featuring an additional pulsating action in the direction of the long axis of the bristles. This brush, the Braun Oral-B 3D Plaque Remover, has been shown in a robot study to remove significantly more plaque substitute than its predecessor, the D9<sup>10</sup> and therefore it would be anticipated that it would also offer a significant advantage in clinical use. This hypothesis is supported by the results of the study reported here which found the 3D to remove significantly more plaque from "all surfaces combined" and from "all interproximal surfaces". The latter observation is particularly important as the 3D action was developed in order to enhance plaque removal from hard to reach sites such as occlusal fissures and interproximal surfaces. The

results of both the robot study<sup>10</sup> and our clinical study suggest that this objective has been achieved.

The results of the study reported here are also important as they validate the laboratory robot study design that was developed in order to allow rapid evaluation of power toothbrushes.<sup>8</sup> This laboratory method of assessing plaque removal efficiency mimics the way a toothbrush is used clinically, but totally controls the way the teeth are brushed, as well as the brushing time and brushing force. It was anticipated that the results from the robot studies would accurately reflect the clinical situation and the results of the study reported here confirm this.

Particular confidence may be placed in the results from the study reported here as in contrast to all other clinical studies comparing toothbrush efficacy, it was possible to use a double blind cross-over design where neither the examiner nor the subject was aware of which toothbrush action was being used. This was achieved by developing an experimental brush, featuring a switch that converted it from the conventional oscillating/rotating action of the D9 to the new 3D action with pulsating movement of the brush head in the direction of the bristles.

It has previously been reported that despite power toothbrushes automatically conferring good brushing technique on the user, better results can be achieved with proper training and the use of professional instruction.<sup>1</sup> This is supported by the findings of the study reported here, where removal of interproximal plaque was observed to be higher in the second phase of the study after subjects had used the power toothbrush for an additional 2 weeks.

It is concluded that the additional pulsating action of the Braun Oral-B 3D Plaque Remover enhanced plaque removal from all sites in the mouth, the advantage in favor of the 3D being statistically significant ( $P < 0.05$ ) when analyzed for the whole mouth, the upper jaw, and all interproximal surfaces. For interproximal surfaces, the 3D removed 60.5% of

plaque compared to 56.5% for the D9, a difference that was highly statistically significant ( $P = 0.009$ ).

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## **SLIP SHEET**

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## Clinical plaque removing efficacy of a new power toothbrush

Ernst, C.-P. et al.  
Johannes-Gutenberg-University, Mainz, Germany  
Am. J. Dent., 1998; In press

### Objectives

To evaluate the effect on plaque removal of adding a pulsating action in the direction of the long axis of the bristles to the established oscillating/rotating action of the Braun Oral-B Ultra Plaque Remover (D9)

### Design

Double-blind, randomized, clinical, crossover study

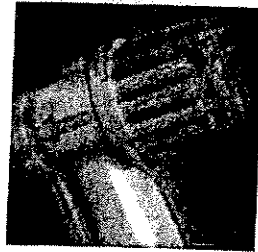
### Materials and Methods

Thirty-two healthy volunteers without any dental training (age  $28.9 \pm 8$  years), participated in the study. They were all in good general health and had at least 20 natural teeth without a removable denture. The volunteers were trained in the use of an oscillating/rotating electric toothbrush (Braun Oral-B Ultra Plaque Remover - D9) 2 weeks prior to the start of the study, at which point all the volunteers received a D9 which they used for the duration of the study.

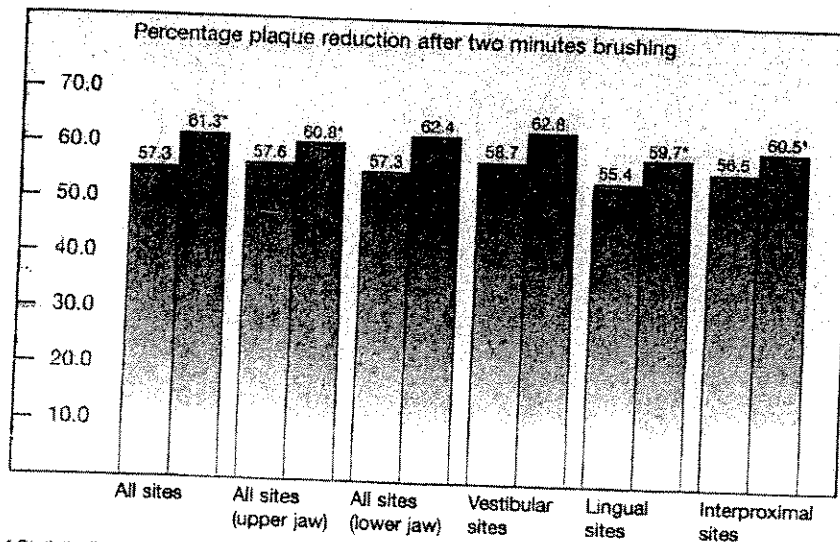
At the first appointment, volunteers were examined and underwent professional prophylaxis. They were then asked to refrain from any kind of oral hygiene for 48 hours. After this period, a plaque score (modified Quigley Hein) was taken separately for the mesiobuccal, buccal, distobuccal, mesiolingual, lingual and distolingual tooth surfaces. A specially designed experimental electric toothbrush based on the D9, but with an additional sonic frequency pulsating action in the direction of the long axis of the bristles was used in the study. The pulsating action of the brushhead could be switched on by means of a control device giving the toothbrush the action of the new Braun Oral-B 3D Plaque Remover. Throughout the study, both the subjects and the examiner were unaware of what mode the brush was operating in. Subjects brushed their teeth with the electric toothbrush in one of the two modes for exactly 120 seconds under the supervision of another examiner, after which the plaque index was again taken. New brushheads were used for each volunteer. After a further 14 days and following a 48 hour period of abstinence from oral hygiene, the procedure was repeated with the toothbrush in the other mode. The difference in plaque reduction with and without the additional pulsating action of the 3D was statistically analyzed using the Wilcoxon test at a significance level of 5%.

# BRAUN

## Oral-B

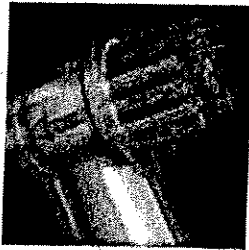


### Results



**BRAUN**

**Oral-B**



When compared with the established Braun Oral-B Ultra Plaque Remover (D9), which has a conventional oscillating/rotating action, the addition of the pulsating action of the 3D resulted in increased efficacy with respect to plaque removal. When analyzed for all sites combined and for all individual sites, the 3D action was found to be superior to that of the D9. For all sites combined, all sites in the upper jaw, all lingual sites and all interproximal sites, the difference between the two groups was statistically significant ( $p < 0.05$ ).

#### **Clinical comment**

This clinical study is unique in that it used a specially developed version of the Braun Oral-B Ultra Plaque Remover (D9) that could be switched to add a pulsating action, thus converting it into the 3D action. The study was therefore carried out double-blind with neither the volunteer nor the examiner knowing which brush action was being used. For this reason one can be confident that the finding of greater efficacy with the 3D action is a true result and is not caused by study bias. The novel pulsating action of the 3D in the direction of the long axis of the bristles was developed to enable deeper cleaning at sites that are difficult to reach, such as occlusal fissures and interproximal surfaces. The results of this study indicate that deeper cleaning is achieved with the 3D which was significantly more effective than the D9 at interproximal surfaces.